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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,121	04/16/2004	Dietrich Hafner	P66087US2	7966

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,121

Applicant(s)

HAFNER, DIETRICH

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

Receipt of Preliminary Amendments filed 4/16/04 is acknowledged. Claims 10-19 are pending in this application. Claims 1-9 stand cancelled.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/160100, filed 4/16/04, issued as US Patent No. 6,858,223; 09/701574, filed 12/8/00, now abandoned, which is a 371 of PCT/EP99/04276 filed 6/19/99. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or

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120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,858,223. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 10 is directed to a composition for the treatment of IRDS or ARDS comprising a) a compound of formula I (phenylaminothipheacetic acids and derivatives thereof); b) lung surfactant comprising a mixture of phospholipids; and c) lung surfactant protein, wherein the lung surfactant protein is a recombinant SP-C derivative which differs from human SP-C by replacement of the two cysteines (in positions 4 and 5) by phenylalanine and replacement of the methionine in position 32 by isoleucine.

US patent '223 claim 1 is directed to a composition for the treatment of IRDS and ARDS comprising a) a compound of formula (phenylaminothipheacetic acids and derivatives thereof) and b) a phospholipid comprising lung surfactant. Claim 2 is directed to a composition wherein the lung surfactant comprises a mixture of phospholipids. Claims 5 and 10 are directed to a composition, which further comprises lung surfactant protein. Claim 6 and 11 are directed a composition, wherein the lung surfactant protein is a member selected from the group consisting of SP-B, SP-C and a modified derivative of either.

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Instant claim 12 and 17 are directed to the method of treating a patient afflicted with IRDS or ARDS, which comprises administering to said patient an effective amount of a composition as claimed in claim 10.

US patent '223 claims 13 and 14 are directed to a method of treating a patient afflicted with IRDS or ARDS, which comprises administering to the patient an effective amount of a composition as claimed in claim 1.

Instant claims 13 and 18 are directed to a method of elevating the arterial oxygen partial pressure in patients afflicted with IRDS or ARDS, which comprises administering to said patient an effective amount of a composition as claimed in claim 10.

US patent '223 claim 16 is directed to a method of elevating the arterial oxygen partial pressure in patients afflicted with IRDS or ARDS, which comprises administering to the patient an effective amount of a composition as claimed in claim 1.

Instant claims 14 and 19 are directed to a method to inhibit (or minimize) the formation of hyaline membranes in lungs of a patient afflicted with IRDS or ARDS, which comprises administering to said patient an effective amount of a composition as claimed in claim 10.

US patent '223 claim 17 is directed to a method to inhibit (or minimize) the formation of hyaline membranes in the lungs of patients afflicted with IRDS or ARDS, which comprises administering to the patient an effective amount of a composition as claimed in claim 1.

The instant application and US '223 differ in that US '223 independent claim 1 does not claim component (c), a recombinant SP-C derivative which differs from human SP-C by replacement of the two cysteines (in positions 4 and 5) by phenylalanine and replacement of the methionine in position 32 by isoleucine. However, claims 10 and 11 of US '223 claims a composition further comprising a lung surfactant protein selected from SP-B, SP-C and a modified derivative of either. Although, US '223 does not specify the SP-C modified derivative, the specification of US '223 defines the recombinant SP-C derivative as a recombinant SP-C derivative which differs from human SP-C by replacement of the two cysteines in position 4 and 5 by phenylalanine and replacement of the methionine in position 32 by isoleucine. See column 4, lines 2-8. It should be noted that the specification may be used to define a term. Thus, the

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instant application and US '223 are obvious variants wherein a method of treating and a composition comprising the three critical elements of compound of formula I; phospholipids lung surfactants; and a lung surfactant protein is claimed.

It should be noted that although applicant has filed the instant application as a divisional of application 10/160,100, now US 6,858,223, a restriction requirement was not made in application 10/160,100. Therefore, a double patenting rejection is proper.

Conclusion

All the claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

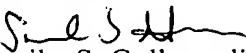
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Sharmila S. Gollamudi
Examiner
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